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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,094	09/22/2003	Rongxiang Xu	27348.702.401	1858
21971 7590 06/20/2005 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER DAVIS, RUTH A	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,094

Applicant(s)

XU, RONGXIANG

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☒ Claim(s) 38,39,50 and 51 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claims 38 – 39 and 50 – 51 are objected to because of the following informalities:

In line 1, the term “puppy” should be spelled correctly as “poppy”.

Claims 50 and 51 are duplicate claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition however are rendered vague and indefinite because it is unclear if the claimed amount of 0.5 – 50% refers to the amounts of oil and wax together, or the wax alone.

Claims 24, 29, 34, 39, 41, 43 and 45 are rendered vague and indefinite because it is unclear if the recited 1 – 50% by weight refers to the amount of the extract and oil together, or the extract alone.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 11, 13 – 14, 17 – 18, 20 – 21, 23 – 26, 28 – 31, 33 – 35 and 38 – 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu (US 5405608 A).

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight. The sterol is present at 0.5 – 20% or 1 – 10 %; the edible wax is present at 3 – 30%, 5 – 20%, or 6 – 10%; the edible wax is selected from beeswax, castor wax, glycowax and carnauba wax, specifically beeswax; the edible oil is from an animal or plant, selected from corn oil, wheat germ oil, soy bean oil, rice bran oil, rapeseed oil, sesame oil and fish oil, specifically sesame oil. The composition contains less than 1% or 0.1% water; the sterol is an animal sterol or phytosterol, selected from stigmasterol, campesterol, beta-sitosterol, chalinosterol, clionasterol, brassicasterol, alpha spinasterol, dancosterol, desmosterol, poriferasterol, natural, synthesized or isomeric forms or derivatives thereof, specifically the sterol is betasitosterol. The composition further comprises an extract of huang qin (*Scutellaria baicalensis* Georgi) wherein the huang qin is selected from a disclosed group; an extract of huang bai (*phellodendron amurense* Rupr) wherein the huang bai is selected from a disclosed group; an extract of huang lian (*coptis chinensis* Franch) that is selected from a disclosed group; an extract

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of poppy capsule; and an extract of earthworms. The components are in aqueous solution, organic solvent or a combination, and are present in an amount of 1 – 50% based on the amount of sesame oil. The composition further comprises baicalin, obaculactone, and obabenine. The edible wax is in microcrystal form at ambient temperature; is beeswax; is in a microcrystal form of beeswax is 0.1 – 100 micrometers in length; is at least two microcrystals of beeswax aggregate to form a complex; the microcrystals of beeswax are dispersed uniformly in the edible oil; the edible oil, edible wax and sterol compound are homogenized to form a colloid with microcrystal forms of edible wax at ambient temperature; and the composition further comprises a pharmaceutically active ingredient.

Xu teaches a composition comprising an edible oil, 3 – 15% edible wax and at least 0.20% sterol (abstract, col.5 line 33-36), a pharmaceutically active agent. The sterol is present at 0.20% or more (col.5 line 33-36) and the edible wax is present at 3 – 15% (abstract). The wax beeswax; the oil is sesame oil (abstract); the composition no more than 0.01% water (col.3 line 9-11); and the sterol is a phytosterol, beta-sitosterol (col.5 line 1-5, 33-35). The composition further comprises huang qin selected from the claimed group, huang bai selected from the claimed group, hugna lian selected from the claimed group, earthworm and poppy capsule; each of which are in aqueous solutions of sesame oil, and in amounts of 2 – 10% based on the weight of the oil (col.2).

While the reference does not specifically identify the composition comprising baicalin, obaculactone, and obabenine, each of the claimed ingredients are present in the instant extracts. Specifically, baicalin is present in huang qin, obaculactone is present in huang bai, and

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obabenine is present in huang lian. Thus the reference composition inherently contains these ingredients.

In addition, although the reference does not specifically identify that the beeswax is in the claimed forms (microcrystal, aggregates, uniformly dispersed microcrystals), the compositions are the same and are combined in the same way (examples). Thus the composition of the cited reference must necessarily also have the same characteristics.

Finally, while the reference does not specifically identify the composition is suitable for oral administration, the compositions are the same, thus the reference composition must also be suitable for oral administration.

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 21, 22, 26, 27, 31, 32, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu.

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at

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least 0.1% by weight. The composition further comprises baicalin at 0.01 – 5% of the composition; obaculactone in an amount of 0.01 – 50%; obabenine in an amount of 0.001 – 5%; berberine at about 0.001 – 5%; and narcotoline at about 0.001 – 2% of the composition

Xu teaches a composition comprising an edible oil, 3 – 15% edible wax and at least 0.20% sterol (abstract, col.5 line 33-36). The composition further comprises huang qin, huang bai, hugna lian and poppy capsule. ^

Although the reference does not specifically identify the composition comprising baicalin, obaculactone, obabenine, berberine and narcotoline in the claimed amounts, each of the claimed ingredients are present in the instant extracts. Specifically, baicalin is present in huang qin, obaculactone is present in huang bai, obabenine is present in huang lian, berberine is present in huang bia and huang lian, and narcotoline is present in poppy capsule. Thus the reference composition inherently contains these ingredients.

Xu does not teach the composition comprising the claimed amounts of baicalin, obaculactone, obabenine, berberine and narcotoline. However, since the reference composition must inherently contain the claimed components, it must also have the same amounts of each component since the extracts are made and combined in the same manner as claimed. Even if the amounts are not exactly the same, it would have at least been obvious to one of ordinary skill in the art that the composition of Xu would have some variable amount of the claimed components as a matter of fact. Therefore, at the time of the claimed invention it would have been obvious to one of ordinary skill in the art to optimize the amounts of the claimed components with a reasonable expectation for successfully obtaining the effective composition of Xu.

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8. Claims 1 – 11, 13 – 16, 48 – 53 and 55 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6306435 B1).

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight. The sterol is present at 0.5 – 20% or 1 – 10 %; the edible wax is present at 3 – 30%, 5 – 20% or 6 – 10%; the edible wax is selected from beeswax, castor wax, glycowax and carnauba wax, specifically beeswax; the edible oil is from an animal or plant, selected from corn oil, wheat germ oil, soy bean oil, rice bran oil, rapeseed oil, sesame oil and fish oil, specifically sesame oil. The composition contains less than 1% or 0.1% water and is formulated into oral dosage form selected from tablets, pills, dragees, capsules, emulsions, gels, syrups, slurries, and suspensions, specifically soft or hard gel capsules. The edible wax is in microcrystal form at ambient temperature, is beeswax; the microcrystal form of beeswax is 0.1 – 100 micrometers in length; at least two microcrystals of beeswax aggregate to form a complex; and the microcrystals of beeswax are dispersed uniformly in the edible oil. The composition further comprises a pharmaceutically active ingredient wherein the wax is beeswax, the active ingredient is selected from a disclosed group, is salicylate, specifically aspirin.

Chen teaches oral compositions for treating gastrointestinal disorders (col.4 line 30-31) wherein the active ingredient is embedded in an oily matrix (abstract). The oily matrix is comprised of animal or plant oils, waxes and sterols (col.3 line 38-45), and is formed into a hard or soft gel capsules (col.3 line 60-65). Water contents are disclosed not to exceed 1.4% (col.4 line 19-21). Chen teaches suitable oils include animal oils, rapeseed oil, corn oil, sesame oil and

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soybean oil (col.5 line 33-40). Suitable waxes include carnauba wax, beeswax and microcrystalline wax (col.5 line 40-44). The active ingredient may be aspirin (col.3 line 15-35)

Chen does not teach each of the claimed amounts of ingredient amounts, or wherein the beeswax has the claimed forms. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize effective amounts of the claimed ingredients as they were known to be result effective variables. In addition, although the reference does not specifically identify that the beeswax is in the claimed forms (microcrystal, aggregates, uniformly dispersed microcrystals), the compositions are the same and are combined in the same way (examples). Thus the composition of the cited reference must necessarily also have the same characteristics. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the teachings of Chen with a reasonable expectation for obtaining an effective composition for treating gastrointestinal disorders.

9. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen and Sosnowski (US 4382886).

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight; and further comprising propolis at 0.1 – 30% of the composition.

Chen teaches oral compositions for treating gastrointestinal disorders (col.4 line 30-31) wherein the active ingredient is embedded in an oily matrix (abstract). The oily matrix is comprised of animal or plant oils, waxes and sterols (col.3 line 38-45).

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Sosnowski teaches oral compositions for treating gastrointestinal disorders (col.12 line 17-26) comprising propolis (abstract, examples).

The above references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for the same purpose of treating gastrointestinal disorders. Although the references do not teach the claimed amounts of ingredients, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of the claimed ingredients as they were known to be result effective variables. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references and routine practice to combine and optimize the amounts of the claimed ingredients with a reasonable expectation for obtaining an effective composition for treating GID.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

10. Claims 1, 21 – 36, 40 – 41 and 44 – 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen and Niazi (US 6365198 B1).

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Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight. The composition further comprises baicalin at at 0.01 – 5% of the composition; obaculactone in an amount of 0.01 – 50% of the composition, obabenine at 0.001 – 5% of the composition, berberine at about 0.001 – 5% of the composition. The composition further comprises an extract of huang qin selected from a disclosed group, huang bai selected from a disclosed group, an extract of huang lian selected from a disclosed group, and/or an extract of earthworms; wherein each of the ingredients are in an aqueous solution, organic solvent or combination, and are present in an amount of 1 – 50% in sesame oil.

Chen teaches oral pharmaceutical bases for use in treating gastrointestinal disorders (col.4 line 30-31) wherein the active ingredient is embedded in an oily matrix (abstract) comprised of animal or plant oils, waxes and sterols (col.3 line 38-45). Chen teaches suitable oils include animal oils, rapeseed oil, corn oil, sesame oil and soybean oil (col.5 line 33-40).

Niaza teaches a composition for treating gastrointestinal disorders in humans, comprising huang qin from the disclosed group, huang lian from the disclosed group), huang bo (hunag bai) from the disclosed group, and Pheretima (earthworm) (abstract, col.7-8). The composition is an alcoholic extract (or aqueous extract) of the ingredients dissolved in vegetable oil (abstract). Although the Niaza does not specifically identify the composition comprising baicalin, obaculactone, obabenine and berberine in the claimed amounts, each of the claimed ingredients are present in the instant extracts. Specifically, baicalin is present in huang qin, obaculactone is present in huang bai, obabenine is present in huang lian, and berberine is present in huang bia and huang lian. Thus the reference composition inherently contains these ingredients.

The above references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for the same purpose of treating gastrointestinal disorders. Although the references do not teach the claimed amounts of ingredients, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of the claimed ingredients as they were known to be result effective variables. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references and routine practice to combine and optimize the amounts of the claimed ingredients with a reasonable expectation for obtaining an effective composition for treating gastrointestinal disorders.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

11. Claims 1, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen and Nakamura et al. (JP 09208598).

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight; wherein the sterol is animal or a phytosterol selected from stigmasterol,

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campsterol, beta-sitosterol, chalinosterol, clionasterol, brassicasterol, alpha spinasterol, dancosterol, desmosterol, poriferasterol, natural, synthesized or isomeric forms or derivatives thereof, specifically betasitosterol.

Chen teaches oral compositions for treating gastrointestinal disorders (col.4 line 30-31) wherein the active ingredient is embedded in an oily matrix (abstract). The oily matrix is comprised of animal or plant oils, waxes and sterols (col.3 line 38-45).

Nakamura teaches a composition for treating gastrointestinal disorders wherein the active ingredient is betasitosterol.

The above references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for the same purpose of treating gastrointestinal disorders. Although the references do not teach the claimed amounts of ingredients, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of the claimed ingredients as they were known to be result effective variables. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references and routine practice to combine and optimize the amounts of the claimed ingredients with a reasonable expectation for obtaining an effective composition for treating GID.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Thus, the

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invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

12. Claims 1 and 17 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen, Nakamura and Kitano (JP 61050919).

Applicant claims a composition comprising and edible oil homogenized with an edible wax, at a concentration of 0.5 – 50% by weight, and a sterol compound at a concentration of at least 0.1% by weight; wherein the sterol is animal or a phytosterol selected from stigmasterol, campesterol, beta-sitosterol, chalinosterol, clionasterol, brassicasterol, alpha spinasterol, dancosterol, desmosterol, poriferasterol, natural, synthesized or isomeric forms or derivatives thereof, specifically a combination of stigmasterol, beta sitosterol and campesterol.

Chen teaches oral compositions for treating gastrointestinal disorders (col.4 line 30-31) wherein the active ingredient is embedded in an oily matrix (abstract). The oily matrix is comprised of animal or plant oils, waxes and sterols (col.3 line 38-45).

Nakamura teaches a composition for treating gastrointestinal disorders wherein the active ingredient is betasitosterol.

Kitano teaches compositions for treating gastrointestinal disorders wherein the active ingredients are phytosterols stigmasterol, brassicasterol, campesterol and/or sitosterol (abstract).

The above references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for the same purpose of treating

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gastrointestinal disorders. Although the references do not teach the claimed amounts of ingredients, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of the claimed ingredients as they were known to be result effective variables. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references and routine practice to combine and optimize the amounts of the claimed ingredients with a reasonable expectation for obtaining an effective composition for treating gastrointestinal disorders.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1 – 11, 13 – 14, 17 – 18, 20 – 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No. 5405608. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the reference does not specifically identify the composition comprising baicalin, obaculactone, and obabenine, each of the claimed ingredients are present in the instant extracts. Specifically, baicalin is present in huang qin, obaculactone is present in huang bai, and obabenine is present in huang lian. Thus the reference composition inherently contains these ingredients. In addition, although the reference does not specifically identify that the beeswax is in the claimed forms (microcrystal, aggregates, uniformly dispersed microcrystals), the compositions are the same and are combined in the same way (examples). Thus the composition of the cited reference must necessarily also have the same characteristics. Furthermore, while the reference does not specifically identify the composition is suitable for oral administration, the compositions are the same, thus the reference composition must also be suitable for oral administration. Finally, although Xu does not teach the composition comprising the claimed amounts of baicalin, obaculactone, obabenine, berberine and narcotoline, it would have at least been obvious to one of ordinary skill in the art that the composition of Xu would have some variable amount of the claimed components as a matter of fact. Therefore, at the time of the claimed invention it would have been obvious to one of ordinary skill in the art to optimize the amounts of the claimed components with a reasonable expectation for successfully obtaining the effective composition of Xu.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
June 10, 2005
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A handwritten signature in black ink, appearing to read 'R. Davis', is positioned to the right of the typed name and date.